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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,461	03/02/2001	Esteban Cvitkovich	13566.105002	9636

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
06/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	09/787,461	CVITKOVICH ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *07 April 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12-17 and 24-35*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). April 7, 2008
13. ☐ Other: _____.

May 28, 2008

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614

Continuation of 3. NOTE: An amendment to claim 12 introduces new matter in that the specification fails to provide support for "3 to 4 weeks." Applicants refer to page 12 of the specification for support. On line 2, page 12, "each cycle is of either 3 or 4 weeks" is recited. Example 1 recites "every 3 or 4 weeks." Examples 2 and 3 recite "every 3 weeks." .

Continuation of 11. does NOT place the application in condition for allowance because: In the last Office Action claims 12-17 and 24-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over both Taamma et al., Eur. J. Cancer, and Riofrio et al., 23rd European Society for Medical Oncology Congress (abstract), in view of Goodman & Gilman. It was asserted Taamma teaches cyclic intravenous administration of Et-743 in the treatment of various solid tumors, such as breast or ovarian cancer, for an infusion time of 24 hours every 3 weeks. The patient population included those who were designated "refractory" to standard chemotherapy, and thus these patients, as required by claim 32, had previously been treated for cancer with chemotherapy. Riofrio teaches an ET-743 dosage range between 600-1800 mg/m2, which encompasses the range recited in independent claim 12, to be administered as an intravenous infusion over 24 hours every 3 weeks to patients with solid tumors in advanced stages. Advanced stage tumors encompass metastatic disease. As required by claim 30, Riofrio includes such tumor types as colorectal, sarcoma, breast, ovary, renal, bladder, gastric, ACUP and larynx. As required by claim 32, all patients were refractory to standard chemotherapy. As required by claims 34 and 35, see the Tables on page 930 in Goodman & Gilman, where dexamethasone is shown to be effective as an antiemetic in cancer chemotherapeutic regimens.
Applicants argue the combination of references fails to teach all of the claimed elements; there is no motivation to combine the references; and the references fail to provide a reasonable expectation of success.
Applicants' argument is not found persuasive and the rejection of record under 35 U.S.C. 103 is maintained. Taamma and Riofrio teach each limitation of claim 12. The Goodman & Gilman reference is applied merely to show the administration of dexamethasone is well established in the prior art as an effective antiemetic agent. Motivation to combine the Riofrio document flows from its disclosure drawn to an effective dosage range of ET-743 and to various tumor types that are responsive to ET-743 therapy. There is a clear reasonable expectation of success because the beneficial administration of ET-743 is taught by Taamma.

Information Disclosure Statements filed April 7, 2008 are acknowledged. The listing of related pending applications has been reviewed.